U.S. Food and Drug Administration

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FDA Prohibits Use of Antiviral Drugs in Poultry to Help Keep Drugs Effective for Humans

The Food and Drug Administration today published a proposed final rule to prohibit the extralabel use in poultry of two classes of approved human antiviral drugs in treating influenza. FDA is taking this measure to help preserve the effectiveness of these drugs for treating or preventing influenza infections in humans.

Specifically, the order prohibits the extralabel use by veterinarians of anti-influenza adamantane (amantadine and rimantadine) and neuraminidase inhibitor (oseltamivir and zanamivir) drugs in chickens, turkeys, and ducks. Extralabel use is the actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling.

"Today's action is a preventive measure designed to protect the public health and illustrates FDA's high level of commitment and key role in preparing for a possible influenza pandemic, which is a top priority for our nation" said Acting FDA Commissioner Dr. Andrew von Eschenbach.

Currently, no drugs are approved for the treatment or prevention of influenza A in animals. However, two classes of antiviral drugs are approved in the United States for the treatment or prevention of influenza A in humans. Under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) veterinarians can legally prescribe these human antiviral drugs to protect animals from influenza (www.fda.gov/cvm/amducatoc.htm.)

Under AMDUCA and its implementing regulations, FDA can issue an order prohibiting certain extralabel uses in animals if such extralabel use presents a risk to the public health. FDA has considered all available information and has concluded that the extralabel use of anti-influenza adamantane and neuraminidase inhibitor drugs in chickens, turkeys, and ducks presents a risk to public health. FDA may add other animal species to the prohibited list as new data becomes available.

Thus far, there have been no reported cases of avian influenza H5N1 in the U.S. Nor is FDA aware that there is ongoing extralabel use of these antiviral drugs in the U.S. by poultry producers. However, concerns have been raised by a number of public health organizations, such as the World Health Organization, Food and Agriculture Organization, and the World Animal Health Organization, that the extralabel use of these drugs in poultry could lead to the emergence of resistant strains of type A influenza. This is of particular concern if the avian influenza H5N1 (commonly known as bird flu) that has been identified in other countries were to emerge in the U.S.

Influenza viruses mutate frequently. Some mutations confer drug resistance to influenza viruses. Repeated and improper use of anti-influenza drugs could allow resistant influenza viruses to flourish.

Interested parties may submit comments on this final rule by May 22, 2006. Comments may be submitted electronically through the Federal eRulemaking Portal: www.regulations.gov or to the Agency Web site: www.fda.gov/dockets/ecomments. Written comments may be faxed to 301-827-6870, or delivered by mail or hand to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments must be identified by Docket No: 2006N-0106. The order of prohibition will become effective June 20, 2006, unless FDA revokes the order, modifies it, or extends the comment period.

Additional information on the final rule may be found in the March 22, 2006 *Federal Register* or by contacting Kim Young, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9207, e-mail: kim.young@fda.hhs.gov Information about the pandemic flu may be found at: www.pandemicflu.gov.

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